



Linxian nutrition intervention trials. Design, methods, participant characteristics, and compliance

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Abstract: Two nutrition intervention trials were conducted in Linxian, China, where the esophageal/gastric cardia cancer mortality rates are among the highest in the world and there is suspicion that the population's chronic deficiencies of multiple nutrients are etiologically involved. Both trials were randomized, double-blind, and placebo-controlled, and tested the effect of multiple-vitamin and multiple-mineral supplements in lowering the rates of cancer. In the first trial, the Dysplasia Trial, 3318 individuals with a cytologic diagnosis of esophageal dysplasia received daily vitamin and mineral supplements or placebos for 6 years. The second trial, the General Population Trial, involved 29,584 individuals and used a one-half replicate of a 2(4) fractional factorial design, which enabled the testing of daily supplementation of four different vitamin and mineral combinations and placebo for a period 5 1/4 years. This article describes the design and methods of these studies as well as the baseline characteristics and compliance behavior of the participants in these two trials, the largest cancer chemoprevention studies reported to date.